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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,574	03/31/2004	Sadanandan Bindu	82484	4330
20529	7590	03/29/2007		
NATH & ASSOCIATES 112 South West Street Alexandria, VA 22314			EXAMINER AFREMOVA, VERA	
			ART UNIT	PAPER NUMBER
			1657	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/29/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/813,574	<b>Applicant(s)</b> BINDU ET AL.	
	<b>Examiner</b> Vera Afremova	<b>Art Unit</b> 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 11-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 4-10 as amended (1/12/2007) are under examination in the instant office action.

Claims 1-3 and 11-21 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/27/2006.

#### ***Specification***

The disclosure is objected to because of the following informalities:

Specification is missing address of the depository collection MTCC that is presently claimed. Appropriate correction is required.

#### ***Claim Objections***

Claims 4-10 are objected to because of the following informalities:

Claim 4 contains tying error(S) such as coma in the middle of the claim text, for example: after the phrase degree C in the step (d). Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

##### ***Deposit***

Claims 4-10 remain/are rejected under 35 U.S.C. 112, *first paragraph*, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

At least some of the claims require one of ordinary skill in the art to have access to specific yeast strains MTCC 5155 belonging to the species of *Candida versatilis*. Because the microorganism is essential to the claimed invention, it must be obtainable by a repeatable

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method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by deposit of the microorganism. The specification does not disclose a repeatable process to obtain the microorganism and it is not clear from the specification or record that the microorganism is readily available to the public. For example: the specific strain EMY 505 is obtained by mutagenization and, thus, its method of making is unpredictable. Moreover, it is uncertain if the parent strain CFR 505 is readily available to the public.

The instant rejection may be overcome by establishing that each microorganism identified is readily available to the public and will continue to be so for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer, or by an acceptable deposit as set forth herein. See 37 CFR 1.801-1.809.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or a statement by an attorney of record over his/her signature and registration number, stating that the deposit has been made under the Budapest Treaty and that all restrictions imposed by the depositor on availability to the public of the deposited material will be irrevocably removed upon issuance of the patent would satisfy the deposit requirement. See 37 CFR 1.808.

Because MTCC (Microbial Type Culture Collection and Gene Bank in India) has acquired the status of an International Depository in accordance to the Budapest Treaty, a declaration stating that all restrictions will be irrevocably removed upon issuance of the patent will overcome this rejection. Please, provide the copy of the MTCC deposit receipts.

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Further, if the strain(s) disclosed in the instant specification are identical to the presently claimed strain MTCC 5155, please, provide an evidence (for example: deposit receipts) that would prove the link between the stain designation numbers.

*Indefinite*

Claims 4-10 as amended remain/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation "mutants" in the step (c) in the method of making dough. There is insufficient antecedent basis for this limitation in the claim since the step (a) is limited to only one mutant strain MTCC 5155.

The same rejections are applied to the claims 5-8 that also recite the use of "mutants".

*New matter*

Claims 4-10 as amended are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Insertion of the limitation drawn to the use of a specific yeast strain "MTCC 5155" has no support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are

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there specific examples of the newly limited genus that would show possession of the concept of the use of specific yeast strain "MTCC 5155".

The literal support for the strain identified as "MTCC 5155" is totally missing in the as-filed specification and on the record.

There some exemplified yeast strains that are identified by internal designation numbers EMY 505 and CFR 505 (specification page 6). The specification describes that strain EMY 505 is obtained by mutagenization of if the parent strain CFR 505.

However, the link between the presently claimed MTCC 5155 and the disclosed strains EMY 505 and CFR 505 is not described in the as-filed specification. Applicants have not provided any evidence that would establish the link between the presently claimed strain MTCC 5155 and the disclosed strains EMY 505 and CFR 505.

Thus, the newly inserted limitation drawn to the use of the strain MTCC 5155 is lacking sufficient support. Therefore, the insertion of "MTCC 5155" is considered to be the insertion of new matter in the instant office action for the reasons above.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-10 as amended remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,794,014 (Siren), Quan et al. ("Production of phytase in a low phosphate

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medium by a novel yeast *Candida krusei*". Journal of Bioscience and Bioengineering. 2001. Vol. 92, No. 2, pages 154-160) and Bindu et al. ("A comparative study on permeabilization treatments for in situ determination of phytase of *Rhodotorula gracilis*". Letters in Applied Microbiology. 1998. 27:336-340) as explained in the last office action and repeated herein.

Claims are directed to a method for reducing phytic acid level in food preparation "Chapathi dough" with an yeast strain belonging to the species of *Candida versatilis* wherein the method comprises step of making "Chapathi dough" by mixing wheat flour, water, salt and the yeast strain(s) and storing the "Chapathi dough" at temperature 10-26°C for 0.5-24 hours, thereby obtaining reduction in the level of phytic acid. Some claims are/are further drawn to the use of the yeast strain(s) cells in a permeabilized form obtained by repeated cycles of freeze-thawing.

The cited patent US 4,794,014 (Siren) discloses a method for reducing phytic acid level in food preparations made from phytate-containing materials (IP6 materials) by using yeast cells as a source of phytase (entire document including col. 3, lines 50-65 and col. 5, lines 22-24). The starting IP6 materials include wheat, wheat bran and wheat flour. In particular example the method for reducing phytic acid level comprises step of making dough by mixing wheat flour, water, salt and the yeast strain(s) and storing the dough, thereby, obtaining reduction in the level of phytic acid (examples 4 and 8). The cited patent teaches that phytate hydrolysis occurs at temperature ranges 20-70°C, thus, including the presently claimed temperatures. The yeast culture that is used as a source of phytase is generic and/or belongs to baker's yeast or *Saccharomyces*. Thus, the cited patent is lacking particular disclosure about the use of yeast cells belonging to *Candida*.

However, the reference by Quan et al. demonstrates that yeast cells belonging to *Candida* produce high level of phytase (abstracts) and they are capable of biodegrading phytate in food materials including wheat. In particular example wheat phytate is biodegraded or phytate amounts are considerably reduced within 12 hours (fig. 7 and page 159, col. 1, par. 1).

The cited documents US 4,794,014 (Siren) and Quan et al. demonstrate that yeast cells are source of phytase but they are silent about preliminary treatments of yeast cells that are used as source of phytase in the methods for reducing phytic level in food preparation including wheat and/or wheat-containing dough.

However, the reference by Bindu et al. teaches that yeast cells have tough cell walls, that permeabilization treatments provide for a larger amount of released enzymes and that repeated cycles of freeze-thawing are most efficient for enhancing phytase activity in yeast cell preparations (entire document including abstract).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify method for reducing phytic acid level taught by US 4,794,014 (Siren) by using yeast cells belonging to *Candida* with a reasonable expectation of success in reducing phytic acid level in wheat containing food including dough or "Chapathi dough" because it is well known that yeast cells are used for enzymatic reduction of phytic acid levels in various food and that yeast cells belonging to *Candida* are source of phytase having high enzymatic activity. One of skill in the art would have been motivated to enhance enzymatic activity of yeast cell preparations by permeabilizing yeast cells through repeated freeze-thaw cycles for the expected benefits in increasing levels of phytate biodegradation.

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Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

### ***Response to Arguments***

Applicant's arguments filed 1/12/2007 have been fully considered but they are not persuasive.

Applicants argue that the cited prior art does not teach or suggest the use of claimed strain MTCC 5155 belonging to the species of *Candida versatilis* (response page 12-14) and the use of the presently claimed strain relates to an improvement over the prior art (response page 14). Yet, neither improvements over the art nor possession of the claimed strain have been established by applicants on the record in order to consider the possibilities of unexpected results and/or effects, if any. Thus, the prior art that teaches the use of yeasts including yeasts belonging to *Candida* in the method for making dough and reducing phytic contents is considered to be obvious variant of the presently claimed method.

No claims are allowed.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

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March 26, 2007

A handwritten signature in black ink, appearing to read 'V. Afremova', with a long horizontal flourish extending to the right.

VERA AFREMOVA

PRIMARY EXAMINER